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June 29, 2020

VIA CM/ECF
Honorable Joel Schneider, U.S.M.J.
U.S. District Court for the District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-02875-RBK-JS (D.N.J.)

Dear Judge Schneider:

Plaintiffs respectfully submit this reply in further support of Plaintiffs' April 13, 2020 letter brief on "macro" discovery disputes with the Retail Pharmacy and Wholesaler Defendants (ECF 413), and in reply to the response letters submitted by Retail Pharmacy Defendants (ECF 479) and Wholesaler Defendants (ECF 478).

At the outset, Plaintiffs have already sharply narrowed their document requests as to these two groups of defendants. This includes compromises in removing and narrowing requests, and deferral of *all* custodial document requests at this time, obviating the need for Retail Pharmacy and Wholesaler Defendants to collect custodians' ESI and to apply search terms until a later date.

I. "Macro" Discovery Disputes with Retail Pharmacy Defendants

Plaintiffs and Retail Pharmacy Defendants agree there are only two issues in dispute, *viz.*, Retail Pharmacy Defendants' production of their upstream cost data, and what TPPs paid for valsartan. *See* Pls.' Ltr. (ECF 413) at 4; Retail Pharmacy Defs.' Ltr. (ECF 479) at 4.

A. Retail Pharmacy Defendants' Upstream Pricing/Cost Data

This issue is straightforward. For Plaintiffs to calculate disgorgement damages, Plaintiffs need to establish Retail Pharmacy Defendants' profits on their sales of finished-dose valsartan. Profit is function of how much Retail Pharmacy Defendants sold valsartan for, less costs. *See, e.g.*, *In re Actiq Sales & Marketing Practices Litig.*, No. 07-4492, 2014 WL 3572932, at *5-8 (E.D. Pa. July 21, 2014) (denying motion to exclude plaintiff expert's calculation of defendant's profits by reference to defendant's sales of specific drugs, and costs associated with those specific drugs). Thus, Retail Pharmacy Defendants' profits cannot be fully calculated without knowing the costs incurred in obtaining the valsartan which they in turn sold to consumers.

Retail Pharmacy Defendants do not dispute this. Instead, they raise three meritless arguments against the production of this relevant data – relevance, confidentiality, and legal sufficiency of Plaintiffs' claims. None of these is a proper basis to withhold production.

Relevance. Retail Pharmacy Defendants' first argue upstream pricing/cost data is irrelevant. In so arguing, these defendants try to read-out any basis for disgorgement or similar remedies from the Amended Master Economic Loss Class Action Complaint ("the Complaint"). This strained reading of the Complaint must be rejected, both because (i) this issue is being decided in a discovery posture, not on a motion to dismiss or a motion for summary judgment, and (ii) the Complaint clearly seeks all available remedies at law and equity, including disgorgement and similar remedies.

There is no question the Complaint seeks all available remedies at law and equity. *See* ECF 398 at 129 (Prayer for Relief). Disgorgement is an equitable remedy available in *all* instances under the inherent power of this Court. *See, e.g.*, *SEC v. Cavanaugh*, 445 F.3d 105, 121 (2d Cir. 2006) ("federal courts possess authority under the Constitution and the Judiciary Act to impose the equitable remedy of disgorgement"); *SEC v. Hughes Capital Corp.*, 917 F. Supp. 1080, 1085 (D.N.J. 1996) ("Disgorgement of illegally derived funds is a remedy within the equitable powers conferred on [the] Court . . ."), *aff'd*, 124 F.3d 449 (3d Cir. 1997). Thus, Retail Pharmacy Defendants are incorrect to say disgorgement and similar equitable remedies (e.g., restitution) are only available under the unjust enrichment counts. *See* Retail Pharmacy Defs.' Ltr. (ECF 479) at 4.[1] The claim is properly pled, and is a reasonable basis to obtain discovery.

Confidentiality. Retail Pharmacy Defendants' contention that they should not produce cost data because it is so sensitive that *no protective order* is sufficient rings hollow. The Discovery Confidentiality Order entered by this Court allows the parties to designate cost and other data the highest level of confidentiality possible. That was a designation requested by the Defendants for exactly this purpose. Retail Pharmacy Defendants' assertion that *no protective order* is sufficient flies in the face of the inclusion of that high designation level, and is simply speculative. *See* Retail Pharmacy Defs.' Ltr. (ECF 479) at 9 ("A confidentiality provision in a protective order is inadequate to address this concern."). Parties in all sorts of cases, including some of the very same

[1] Even were this not the case, disgorgement or similar remedies are expressly authorized under other pleaded claims for relief, e.g., violations of states' consumer fraud statutes.

defendants in this litigation, produce similarly or more sensitive cost data in all manner of litigation.[2] The production of proprietary data and trade secrets is commonplace in this Court.

Further, pursuant to the Court's protocol, peripheral defendants have already produced pricing and cost data. This includes retail pharmacies. The entities seeking dismissal have had no trouble invoking the Discovery Confidentiality Order, without "upending the entire structure of the generic drug business model." *See* Retail Pharmacy Defs.' Ltr. (ECF 479) at 8. Indeed, in matters such as antitrust cases, competitors often find themselves on the same side and having to produce the same types of sales and pricing data as that at issue here, and protective orders are routinely entered to assuage any confidentiality concerns. *See, e.g., In re Generic Pharms. Pricing Antitrust Litig.*, MDL No. 2724, Pretrial Order No. 7 (protective order governing, *inter alia*, production of sales/pricing data in matter involving more than 20 competitors), *available at* https://www.paed.uscourts.gov/documents/MDL/MDL2724/16md2724%20PTO7.pdf.

Merits-based legal argument. The balance of Retail Pharmacy Defendants' arguments against producing any upstream pricing/cost data collapses into truncated Rule 12(b) arguments, or even Rule 56 summary judgment arguments – all without the inferences accorded in favor of Plaintiffs as the non-moving parties for purposes of Rule 12(b), or without the benefit of a developed discovery record and without regard to genuine issues of material facts for purposes of Rule 56.

While the parties' Rule 12(b) briefing is forthcoming, it suffices to say that Retail Pharmacy Defendants' insinuation that they are completely immune from liability, under any theory of law of any of the fifty states and territories alleged in the Complaint, is simply hyperbole. *See, e.g., In re Nat'l Prescription Opiate Litig.*, No. 17-md-2804, 2020 WL 1669655, (N.D. Ohio Apr. 3, 2020) (sustaining various state law claims against some of the same wholesalers and retail pharmacies present here); *Fagan v. Amerisource Bergen*, 356 F. Supp. 2d 198 (E.D.N.Y. July 29, 2004) (sustaining various state law claims against wholesale distributor which is defendant here). More fundamentally, a "party cannot refuse to produce a requested document or information simply because it is relevant to a claim or defense on which the producing party believes that it will prevail." *Orchestrate HR, Inc. v. Trombetta*, 178 F. Supp. 3d 476, 508 (N.D. Texas 2016) (internal quotations and citation omitted).

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[2] *See In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, No. 17-MD-2785-DDC-TJJ, 2018 WL 3062416, at *4 (D. Kan. June 20, 2018) (overruling confidentiality arguments due to the entry of a protective order and requiring CVS, which was a non-party subpoena recipient in the litigation, to produce not only data from the period of 2013 to 2017, but also documents as well, and requiring them to so produce these documents within 21 days of the Court's Order); *Suture Exp., Inc. v. Cardinal Health, 200, LLC*, No. 12-2760-RDR, 2013 WL 6909158, at *1 (D. Kan. Dec. 31, 2013) (finding that a two-tier confidentiality designation is appropriate for current pricing, and overruling Cardinal's request that historical pricing should considered "highly confidential").

Potential Compromise. It should be noted that cost offsets will be *Defendants'* burden at trial, not Plaintiffs' burden. That is, to support a claim of disgorgement, a plaintiff need only show the value of defendant's sales of tainted products; the defendant bears the burden of reducing sales by costs or other expenses. *See, e.g.*, *Rexall Sundown, Inc. v. Perrigo Co.*, 707 F. Supp. 3d 357, 359 (E.D.N.Y. 2010). If Retail Pharmacy Defendants were to agree to withdraw pertinent defenses, and not to oppose any forthcoming class certification motion on the basis that Plaintiffs' damages estimates do not properly account for Retail Pharmacy Defendants' costs, then the production of cost data can be deferred. Absent this, it is clearly proper for Plaintiffs to obtain discovery of this upstream pricing/cost data. *See, e.g.*, *In re Actiq*, 2014 WL 2572932, at *5-8.

B. Prices Paid By TPPs

The second dispute relates to how much Retail Pharmacy Defendants received from all sources (not just consumers) for valsartan these defendants sold. There are two principle sources of payments at the downstream point-of-sale: consumers and TPPs. Retail Pharmacy Defendants have agreed to produce the portion of the valsartan price that was paid by consumers. *See* Retail Pharmacy Defs.' Ltr. (ECF 479) at 2. While this is helpful, it is only part of the picture. To calculate how much Retail Pharmacy Defendants made in sales, Plaintiffs need the full picture – the total purchase price, how much of the price was paid by consumers, and how much of the price was paid by TPPs. Plaintiffs need this even though the Complaint only alleges claims against Retail Pharmacy Defendants on behalf consumers, not TPPs. Further, at least one additional TPP has filed a lawsuit, since transferred to this MDL, that *does* sue Retail Pharmacy Defendants. *See Employers & Laborers Locals 100 & 397 H. & Welfare Fund and Steamfitters Local 439 v. Zhejiang Huhai Pharm. Co., Ltd., et al.*, No. 3-20-cv-00125 (S.D. Ill.). This TPP may be added to the Complaint to represent TPPs for claims against Retail Pharmacy Defendants and be a part of Plaintiffs' Motion for Class Certification. Regardless, even as the Complaint currently stands, TPPs' damages against the other defendants depends on how much they paid at the retail pharmacy level, so this information is necessary no matter what.

Notably, the total amount paid at dispensement, as well as the amounts paid by each consumer or TPP, appears on consumer pharmacy records maintained by these defendants. Thus, there is little if any incremental burden for Retail Pharmacy Defendants to query one additional field. They do not argue otherwise. And in either case, Plaintiffs have the right to this information insofar as it is relevant to proving the total amount paid by the TPPs, to prove the TPPs' class-wide damages. To reiterate, the measure of TPPs' damages recoverable from the other defendants will be calculated based on how much TPPs paid Retail Pharmacy Defendants.

Retail Pharmacy Defendants' confidentiality concerns as to what TPPs paid are insufficient for the same reasons discussed above. *See supra* Part I.A.

Last, Retail Pharmacy Defendants should not be allowed to withhold data on total price and prices paid by TPPs in discovery, and later hold that against Plaintiffs at class certification. If Retail Pharmacy Defendants are relieved from producing prices paid by TPPs, then they should stipulate they will not oppose class certification or raise defenses on the basis that Plaintiffs lack that information. Alternatively, Retail Pharmacy Defendants should produce aggregated TPP

payment data (e.g., showing total amounts paid by each TPP, not on a transactional basis), but again, only if they agree not to oppose class certification on this basis.

C. Miscellaneous

Since March 2020, Plaintiffs believed the two foregoing disputes were the only ones remaining with Retail Pharmacy Defendants. Retail Pharmacy Defendants' response letter confirms this. Yet, on June 25, Retail Pharmacy Defendants informed Plaintiffs that their defense group intends to propose additional changes to some of the other heretofore undisputed document requests. What cannot happen here is a Court ruling on the teed up macro issues above, but thereafter Retail Pharmacy Defendants propose more changes to other requests, potentially leading to further disputes that will undoubtedly delay the process and lead to more argument before the Court. This RFP process already has dragged on since December 2019 and Retail Pharmacy Defendants have had more than ample time to resolve these minor issues among themselves. Plaintiffs believe the language of *all* requests should be finalized by the July 6 conference. Plaintiffs have repeatedly offered to continue efforts to resolve, informally, the wording of any other requests prior to July 6. But if this effort is unsuccessful as to each Retail Pharmacy Defendant, Plaintiffs respectfully request the Court finalize and enter the document requests to Retail Pharmacy Defendants in their entirety following the July 6 conference.

Finally, since many of these requests were agreed to in all material respects in February, and Retail Pharmacy Defendants have agreed to begin production of these agreed-to documents prior to and irrespective of a ruling on the macro issues, those documents should be produced in the near term without delay. Retail Pharmacy Defendants have had more than sufficient notice and time to organize this production, which should not be delayed further pending resolution and preparation of forthcoming newly ordered discovery following resolution of the macro issues.

II. "Macro" Discovery Disputes with Wholesaler Defendants

A. Wholesaler Defendants' Misapprehension of the Draft RFP and Macro Issue Briefing Process

Wholesaler Defendants' letter response demonstrates their fundamental misunderstanding of the point of the current draft document requests and macro issue briefing process. They claim in their letter that, *even after* the Court resolves macro issues and enters the finalized document requests, Wholesaler Defendants intend to file *additional* objections to the document requests. *See* ECF 478 a 1 n.2 ("Wholesalers have not yet had the opportunity to object to formally-served RFPs….[and] reserve the right to object to the actual RFPs served."). This is apparently an outgrowth of Wholesaler Defendants' view of the world, that they are permitted to sell tens or hundreds of millions of dollars of contaminated drugs with absolute immunity – as if they were the United States Postal Service, simply transporting boxes from place to place.[3]

[3] Even more incredibly, the relief that Wholesaler Defendants seek in their motion is for the Court to enter a protective order "shielding" Wholesaler Defendants' from Plaintiffs *draft requests*. Suffice it to say, not only is it improper to seek the entry of a protective order against *discovery*

The purpose of the draft document requests process is for the parties to resolve all material disputes, so that once the document requests are finalized, the defendants can straight away begin to produce responsive documents in their capacity as Defendants in this litigation. Wholesalers' brazen vision is that after six months of negotiating the draft document requests, they get to extend this preliminary process indefinitely by serving "formal" objections to the RFPs (presumably thirty days after the Court enters the document requests), which will spawn additional meet and confers, and will result in more issues for the Court to decide. Wholesaler Defendants cannot be allowed to push this already-lengthy process out even longer.

B. Matters Not In Dispute

Prior to Plaintiffs' opening letter brief, Wholesaler Defendants had not agreed to *any* of the proposed document requests (even the ones they had proposed themselves). Wholesaler Defendants now agree that the following items are not in dispute: "(1) the definition of valsartan; (2) the discovery 'start' dates, (3) document retention policies . . . .and (4) indemnification agreements[.]" ECF 478 at 2 n.4. And while they do not expressly say so, they only identify four specific requests – all about purchase or sales data – which "remain in dispute." *Id.* at 2. Accordingly, the Court should be able to enter the operative set of document requests, attached to Plaintiffs' Letter at Exhibit C following a decision on these four specific, data-related document requests. Plaintiffs address these four specific requests below.

C. Tracing Data Regarding Wholesaler Defendants' Purchasers of Valsartan (Upstream Purchases)

Request No. 1 seeks tracing data for Wholesaler Defendants' purchases of valsartan.[4] Request No. 3 seeks tracing data for Wholesaler Defendants' downstream sales of valsartan.[5] Collectively, therefore, these two requests seek the documents that will yield the requested data,

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that has not even been served, but it is now obvious that Wholesaler Defendants had absolutely no intention of producing an iota of data absent a court order, calling into question whether the Wholesaler Defendants were negotiating with Plaintiffs in good-faith these last six months.

[4] "For purchases of VCDs by you from Manufacturer Defendants during the time period from January 1, 2012 to December 31, 2019, produce documents sufficient to identify the dates of purchase, the quantities/units purchased, the NDC, batch and lot numbers, and expiration date (to the extent such information is maintained by you in the ordinary course of business and can be obtained following a reasonable search) for the VCDs purchased and the name of the Manufacturer Defendant from whom the VCDs were purchased."

[5] "For sales of VCDs by you to Retail Pharmacy Defendants during the time period from January 1, 2012 to December 30, 2019, documents sufficient to identify the quantities/units sold, the NDC, batch and lot numbers and expiration date (to the extent such information is maintained by you in the ordinary course of business and can be obtained following a reasonable search) and purchaser name."

to track what valsartan Wholesaler Defendants purchased, and in turn to whom they sold that valsartan (e.g., downstream pharmacies), and the key information that came in and then went out.

There can be little question that this data is highly relevant, and in fact at the core of what must be produced. The Court has repeatedly recognized that information to identify and track valsartan in the distribution chain is eminently important in this litigation. The Wholesaler Defendants are in the middle of the supply chain: they buy valsartan from Manufacturer Defendants, and resell it to Retail Pharmacy Defendants. There would be an obvious, highly prejudicial gap in the chain without this appropriate data from Wholesaler Defendants. Wholesalers Defendants' objections to these requests is a clear illustration of the unreasonable pushback that Plaintiffs have been attempting to navigate in an effort to obtain and marshal the fundamental evidence at the core of this litigation.

Wholesaler Defendants' response seeks to evade this simple reality. None of the reasons they proffer explain why they are immune from the basic obligation to produce this clearly relevant data. Plaintiffs address each of Wholesaler Defendants' faulty arguments below.

Merits-Based Legal Arguments Should Be Disregarded. Wholesaler Defendants self-servingly mis-characterize themselves as "innocent sellers" completely immune from any liability whatsoever under any of the laws of the fifty states and territories alleged in the Complaint. As noted above, a party "cannot refuse to produce a requested document or information simply because it is relevant to a claim or defense on which the producing party believes that it will prevail." *Orchestrate HR*, 178 F. Supp. 3d at 508 (internal quotations and citation omitted). And again, it is simply inaccurate for these defendants to claim complete immunity from liability. Many courts have held that parties at the wholesale or distribution level are not immune from all state law liability. *See, e.g.*, *AMC, LLC v. Nw. Farm Food Coop.*, No. 6:17-CV-00119-AA, 2020 WL 485529, at *4 n.2 (D. Or. Jan. 29, 2020) (distributors may be liable for selling dangerous product); *Lindholm v. BMW of N. Am., LLC*, 202 F. Supp. 3d 1082, 1092 (D.S.D. 2016) ("Distributors of a product . . . may be sued for strict liability."); *Williams v. West Penn Power Co.*, 467 A.2d 811 (Pa. 1983) (privity not required to state breach of implied warranty claim against entity in distribution chain); *Krack v. Action Motors Corp.*, 867 A.2d 86, 89 (Conn. App. Ct. 2005) (rejecting defendant's argument that " its innocent sale of a salvaged vehicle to the plaintiff could not have constituted a breach of the implied warranty of merchantability because the plaintiff did not prove that the defendant was at fault in failing to discover the salvage history"). This includes at least one court which held as recently as two months ago that some of these *exact same* Wholesaler Defendants *are not* immune from all state law liability. *In re Nat'l Prescription Opiate Litig.*, 2020 WL 1669655, (N.D. Ohio Apr. 3, 2020) (sustaining various state law claims against some of the same wholesalers and retail pharmacies present here).

The Wholesaler Defendants spend the lion's share of their letter brief previewing their forthcoming 12(b)(6) arguments. However, in so vociferously arguing in such a conclusory fashion that they have no culpability as a matter of law, Wholesaler Defendants demonstrate why their eventual 12(b)(6) arguments on this point will fail, as there are genuine issues of material fact that exist about whether Wholesaler Defendants knew, or should have known, that sub-standard

generic products were being mass produced, as cheaply as possible and flooding the market. These questions can only be assessed after the production of discovery.

Wholesaler Defendants also lean heavily on the so-called innocent seller defense. First, even accepting, *arguendo*, that it is appropriate to brief dispositive briefing issues in a ministerial discovery motion, that defense is not applicable to cases and claims that are not governed by the New Jersey Product Liability Act, using New Jersey Law as a mere illustrative example. It is settled that claims for breach of express warranty are expressly excepted from the scope of the statute. *Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 62 (2008).[6] In fact, in New Jersey, the statutory "innocent seller" defense only applies to "strict liability claims." N.J.S.A. 2A:58C-9. Finally, the defense does not apply, even when the claims are pled to implicate the PLA, where, among other reasons, (1) the manufacturer cannot be identified, (2) "[t]he manufacturer has no known agents, facility, or other presence within the United States," (3) "[t]he manufacturer has no attachable assets...", and under circumstances where the product seller had substantive involvement or "knew or should have known of the defect in the product…." N.J.S.A. 2A:58C-9. At this formative stage, the inferences are drawn in favor of the Plaintiffs, not the Defendants, and when the record is established these issues can be revisited. Moreover, Wholesaler Defendants would be obligated to produce documents and data as third parties, even if they were not named parties in this litigation.

Relevance and Proportionality. Wholesaler Defendants' only retort to the obvious relevance of tracing data is that each defendant *might* not possess *all* of the tracing information Plaintiffs seek. Specifically, they claim the Drug Supply Chain Security Act ("DSCSA") does not *require* them to pass along drug lot numbers to its own downstream customers. *See, e.g.* Wholesaler Defs.' Ltr. (ECF 478) at 4. This red-herring argument overlooks several key points. First, Wholesaler Defendants concede that they *do* receive lot numbers when they purchase drugs from manufacturers. *Id.* at 7 ("It is true that Manufacturers are required to send lot information when selling to Wholesalers"). Wholesaler Defendants also do not dispute that they *do* have data on all the other metrics requested – e.g., NDC number, manufacturer name, quantities, etc. Thus, Wholesalers Defendants should produce the traceability data they do have for the entire relevant period, even if that data might be slightly under-inclusive of what Plaintiffs seek.

As to their downstream sales, Wholesaler Defendants do not dispute (and, at least for McKesson, their own data sample shows) that they maintain all of the data points requested except lot number in their *sales systems*. Again, they argue the DSCSA does not *require* them to provide lot numbers to their downstream customers.

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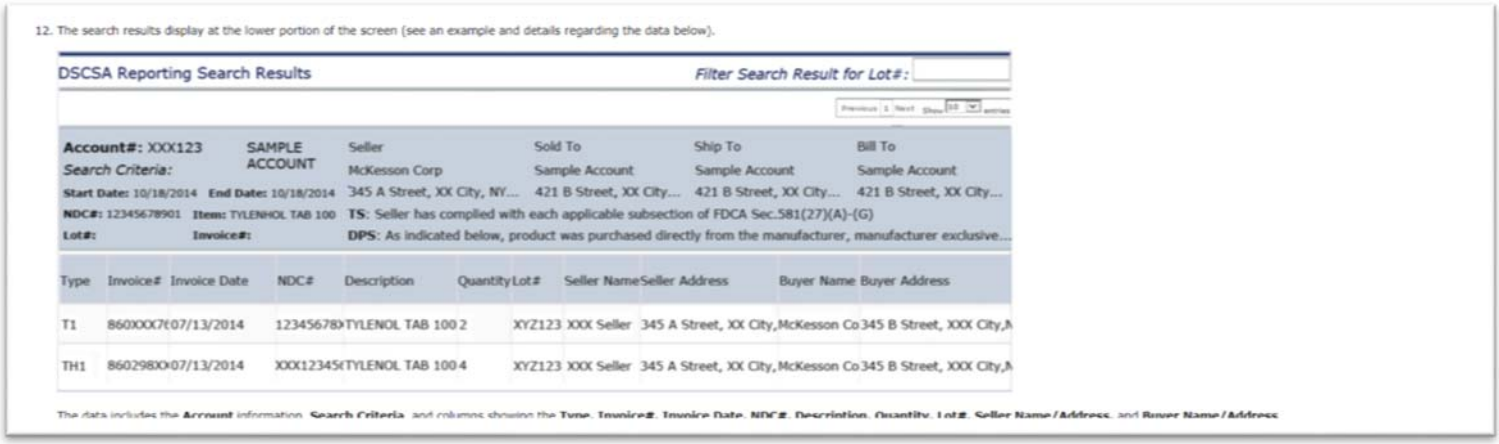
[6] In *Sinclair*, in which the plaintiffs alleged no physical injury but sought medical monitoring for future harm caused by Vioxx, the New Jersey Supreme Court made clear that in a case where no physical injury or damage to "property, other than the product itself," is alleged, as in the economic loss actions here, the PLA does not encompass the claim because it will "not satisfy the definition of harm" under the PLA. *Id*. at 62-64.

As a threshold matter, arguing that the DSCSA does not *require* Wholesaler Defendants to provide lot numbers in their sales systems does *not* mean Wholesaler Defendants have *no* helpful tracing data. Indeed, each Wholesaler Defendant's precisely-worded declarations do *not* say what information they *do* maintain, only that the DSCSA does not *require* them to maintain lot numbers in their *sales* systems. While *sales* systems' data might not track lot number for a given sale, it is highly likely that Wholesaler Defendants maintain separate *inventory data* systems that contain at least *some* information which, while perhaps not definitive, would facilitate understanding which lot numbers of product were shipped to which downstream customers.[7]

Additionally, Wholesaler Defendants completely side-step the reality of the business in which they operate, wherein the demands of their customers dictate how they operate and what data points they keep. It is clear that Wholesaler Defendants are incredibly cognizant of the fact that their retail pharmacy customers are also required to keep additional tracing data in light of the new DSCSA regulations. As such, McKesson advises their customers (retail pharmacies) that this same traceability data not only exists, but is available to be queried and downloaded immediately to them through the McKesson Connect Forum.



12. The search results display at the lower portion of the screen (see an example and details regarding the data below).

DSCSA Reporting Search Results — Filter Search Result for Lot#:

Account#: XXX123 SAMPLE ACCOUNT	Seller	Sold To	Ship To	Bill To	
Search Criteria:	McKesson Corp	Sample Account	Sample Account	Sample Account	
Start Date: 10/18/2014 **End Date:** 10/18/2014	345 A Street, XX City, NY...	421 B Street, XX City...	421 B Street, XX City...	421 B Street, XX City...	
NDC#: 12345678901 **Item:** TYLENHOL TAB 100	**TS:** Seller has complied with each applicable subsection of FDCA Sec.581(27)(A)-(G)				
Lot#: **Invoice#:**	**DPS:** As indicated below, product was purchased directly from the manufacturer, manufacturer exclusive...				

Type	Invoice#	Invoice Date	NDC#	Description	Quantity	Lot#	Seller Name	Seller Address	Buyer Name	Buyer Address
T1	860XXX7(	07/13/2014	12345678	TYLENOL TAB 100	2	XYZ123	XXX Seller	345 A Street, XX City,	McKesson Co	345 B Street, XXX City,A
TH1	86029BX	07/13/2014	XXX12345	TYLENOL TAB 100	4	XYZ123	XXX Seller	345 A Street, XX City,	McKesson Co	345 B Street, XXX City,A

The data includes the **Account** information, **Search Criteria**, and columns showing the **Type**, **Invoice#**, **Invoice Date**, **NDC#**, **Description**, **Quantity**, **Lot#**, **Seller Name/Address**, and **Buyer Name/Address**.

MCKESSON CONNECT, DSCSA TRACEABILITY REPORTING HELP, *available at* https://newordering.mckesson.com/SMOnline/help/ordering/Core_Functions/Reports/DSCSA_reporting.html (last visited June 27, 2020).

McKesson collects and tracks this data not because the DSCSA requires wholesalers to track it, but rather because *it is what their customers want and need.* This reality is starkly contrasted with the alternate universe the Wholesaler Defendants describe in their motion, wherein a routine litigation data request for information related to 193 NDC codes would bring a global drug supply and logistics company to its knees because of the burden. Meanwhile, a pharmacy could run 193 NDC codes through the McKesson Connect portal in a matter of minutes.

[7] The arguments before the Court reflect the meet and confer process wherein Plaintiffs continually requested Wholesaler Defendants to state whether either of the three defendants keep any of this information in the ordinary course of business. In each instance, the response was that the law does not require that it be kept, without answering the question as to whether it is kept.

Because they were incentivized from a business perspective to track data uniformly, all participants in the supply chain (including Manufacturer Defendants, Wholesaler Defendants and Retail Pharmacy Defendants) worked collaboratively to establish consistent and feasible processes with which to capture this data. For instance, manufacturers ship drugs to wholesalers and other customers in packages with bar codes. *See, e.g.*, Ex. A to Pls.' Ltr. (ECF 383) at ¶ 39. These bar codes are readable by scanners upon receipt by a wholesaler for inventory control purposes. *See, e.g., id.* at ¶¶ 36-41. Among the data scanned would be lot number. *Id.* at ¶ 36. These bar codes clearly feed information into an electronic system that can be queried and exported. [8]

Even if this were not the case, defendants are obligated not to sell expired product. *See, e.g.*, 21 C.F.R. 211.137 ("The absence of an expiration date on any drug product packaged after September 29, 1979, except for those drugs specifically exempt by 211.137 (e), (f), and (g), is cause to initiate regulatory action against the product and/or the responsible firm. absence of expiration date."). [9]

For this reason, handlers of drugs often employ inventory systems to ensure the oldest product in inventory is shipped to customers first (e.g., first-in, first-out, or FIFO). *Cf.* Ex. A to Pls.' Ltr. (ECF 383) at ¶¶ 12,40, 42. By way of example, if it is known that a certain lot number was received on a certain date, and that this inventory had to be replenished after 90 days because all of that drug was shipped to three customers, a factfinder can make the reasonable inference that those three customers received drug product from the given lot. Indeed, each Wholesaler Defendants boasts about their own respective proprietary inventory software and ordering systems designed to make tracking and ordering drugs simple and traceable for pharmacies.

For example, McKesson repeatedly describes its proprietary McKesson Inventory Control software as providing "continuous visibility to inventory by quantity, status and location" including "[m]anaging lot control, expiration date, and serialization." [10] Cardinal Health's

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[8] Wholesaler Defendants do not (and cannot) deny that they have been utilizing bar codes to capture data and keep it an electronic database. Wholesaler Defendants have also been actively communicating with Manufacturers about those barcodes to ensure the data the barcodes would send was sufficiently reliable for traceability purposes. *See* G1 2018 UPDATE: IMPLEMENTATION OF DSCSA SERIALIZATION REQUIREMENTS, *available at* https://www.gs1us.org/documents?Command=Core_Download&EntryId=1511 ("We have had conversations with about 50 manufacturers, to date, providing specific feedback on the barcode data we captured.")

[9] *See also, e.g.*, CVS PHARMACY REPRIMANDED FOR DISPENSING EXPIRED DRUGS (June 7, 2019), *available at* https://www.wcnc.com/article/news/cvs-pharmacy-reprimanded-for-dispensing-expired-drugs/275-ba087475-1647-4096-af7f-5be3761f47fb.

[10] *See* MCKESSON HEALTHCARE WAREHOUSE MANAGEMENT, *available at* https://www.mckesson.com/documents/providers/fact-sheet---mckesson-healthcare-warehouse-management/ (last accessed June 26, 2020).

Inventory Management Solution purports to be so highly technical that it "proactively locate[s] soon-to-be-expired product" and provides "real-time, end-to-end visibility."[11] Amerisource Bergen describes "data analytics" services they provide, including "niche premium logistics services" and inventory and pharmacy management.[12]

While, noticeably, none of the Wholesaler Defendants address their inventory systems in their response letter or declarations, in public comments and interviews touting the innovations of their companies, many of the declarants are very solicitous in providing information about these very inventory management systems and describing how product serialization and tracing is not only good business, but promotes favorable patient outcomes. In a blog advertising McKesson's inventory software solutions,[13] Declarant Scott Mooney describes his favorite part of his job as working with pharmacies on "standardizing product definitions and identifiers" and "helping [pharmacies] to use technology to check a drug before…giv[ing] it to a patient." Mooney goes on to say that it is important to have product definitions and identifiers on prescription drugs because it allows dispensers to "spot counterfeit drugs" in the supply chain and "recall a portion of a batch made during some time frame of one day at one plant." [14] Mooney concludes by proclaiming that unique identifiers turn the supply chain into a positive force to "improve patient outcomes." This is a far cry from the grim picture Mooney paints in his declaration filed with the Court, wherein he states that requiring companies like McKesson to trace lot number would "burden the supply chain, slowing down shipments" which would, in turn, negatively impact delivery of pharmaceuticals to "patients in need." (Mooney Decl. ¶ 53).

While Amerisource Bergen's declarant, Matthew Sample, told the Court that precise drug product tracking served "no commercial" purpose to Amerisource Bergen because it "burdened the supply chain, slow[ed] down shipments," and "impacted delivery of pharmaceutical patients in need (Sample Decl. ¶ 6), Sample actually previously conducted an entire presentation on the "opportunities" created by serialization and traceability at the First Annual International

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[11] *See* PROOF POSITIVE, *available at* https://www.cardinalhealth.com/content/dam/corp/web/documents/case-study/cardinal-health-adventist-health-white-memorial-case-study.pdf (last accessed June 26, 2020).

[12] *See* https://s24.q4cdn.com/386340686/files/doc_downloads/proxy_materials/ABC_2018_10_K.pdf (last accessed June 26, 2020).

[13] McKesson is the only one of the three to provide any data excerpt whatsoever, and that is a couple of lines from its sales (not any of its inventory) systems.

[14] *See* MCKESSON RAISING SUPPLY CHAIN STANDARDS AT HEALTH SYSTEM AND HOSPITAL PHARMACIES (Aug. 19, 2019), *available at* https://www.mckesson.com/Blog/Supply-Chain-Health-System-Hospital-Pharmacies/ (last visited June 28, 2020).

Conference on Supply Chain Security and Management in 2017.[15] Further, all three Wholesaler Defendants have collaborated on barcoding at the product level; these barcodes include, among other information, expiration dates for product – something they speciously claim here they do not trace.[16]

Wholesaler Defendants' pleas that they have no way to track or infer lot number and expiration date for drugs they sell is all the more implausible given that the FDA has cited McKesson for failing to do this. In February 2019, the FDA issued a Form 483 warning letter to McKesson because McKesson failed to keep appropriate records for certain drugs it sold to retail pharmacies.[17] The FDA specifically cited an instance in December 2016 in which Albertsons (a Retail Pharmacy Defendant) reported that it received losartan from McKesson without any lot number or expiration date. *Id.* Product without expiration dates or lot numbers on the packaging are considered "illegitimate" and must be reported to the FDA. *Id.* The FDA cited this violation, among others, in finding that McKesson "failed to have systems in place to enable compliance with [] verification requirements" to ensure that illegitimate or suspect product is not dispensed to a patient. *Id.* The FDA's admonitions further drive home the point that all members of the drug supply chain must have *some* tracing information.[18]

In short, Wholesaler Defendants' relevancy argument is misguided. They clearly possess most if not all of the information sought. That they might not be statutorily required to maintain one datapoint (lot number) in their downstream sales database does not mean (and they certainly do not say) that they do not possess next-best inventory systems data that will shed light on which drugs (by lot number or otherwise) were sold to which downstream customers. They would have

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[15] *See* 1ST ANNUAL INTERNATIONAL CONFERENCE ON SUPPLY CHAIN SECURITY AND MANAGEMENT, *available at* https://www.pharmaconference.com/Brochures_PDF/Pharm_conferences/Supply%20Chain%20Mgt%2010-17%20Brochure%206-12-17.pdf (last visited June 26, 2020).

[16] *See, e.g.*, 2019 UPDATE: BARCODE READABILITY FOR DSCSA 2023 INTEROPERABILITY, *at* https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=1933&language=en-US&PortalId=0&TabId=134 (last visited June 29, 2020).

[17] *See* FDA Warning Ltr. to McKesson (Feb. 7, 2019), *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mckesson-corporation-headquarters-2719-565854-02072019 (last visited June 28, 2020).

[18] In a statement regarding this enforcement action, former FDA Commissioner Scott Gottlieb did not mince his words, describing McKesson's conduct as "simply unacceptable" because a "distributor's failure to have systems in place to investigate and quarantine suspect and illegitimate products within their control is a violation of the law." *See* STATEMENT FROM FDA COMMISSIONER SCOTT GOTTLIEB (Feb. 12, 2019), *available at* https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-ongoing-efforts-stop-spread-illicit-opioids-further (last visited June 29, 2020).

this Court believe that they keep *less* inventory-level data for prescription drugs (one of the most heavily regulated fields of commerce) than other companies keep for cans of lima beans.

Confidentiality. The Court need not dwell on Wholesaler Defendants' confidentiality concerns which are squarely addressed by the Discovery Confidentiality Order. As discussed *supra* Part I.A, protective orders adequately address confidentiality concerns about commercially sensitive data produced by defendants in multi-party actions – that is why the order was implemented, to facilitate discovery. Other defendants, including peripheral defendants seeking dismissal, have already produced the same types of data Wholesaler Defendants claim is simply too sensitive to be produced by them.

Undue Burden. Only one of the three Wholesaler Defendants – McKesson – argues undue burden.[19] *See* Wholesaler Defs.' Ltr. (ECF 478) at 9. McKesson astonishingly states it has a single employee who is able to query the pertinent data. *See* ECF 478, Ex. B at ¶ 36 ("There is one, specific McKesson representative ('Rep') who is able to access the BHP System to create a resulting purchase report"). McKesson claims it will take this one employee, working full-time, almost *1.5 years* to pull data sufficient to show its purchases and sales of Manufacturer Defendants' valsartan.[20] *Id.* This arithmetic legerdemain lacks plausibility. For starters, McKesson's own declarant does *not* state that it will take 1.5 years to do the work – that is defense lawyers' math. *Compare* ECF 478 at 9 (letter), *with* Ex. B thereto at ¶ 47 (declarant). Second, no facts suggest McKesson bought 193 different types of valsartan. Third, McKesson's declarant does not elaborate as to *why* it takes *3 hours* to input a single NDC number and run a report. Finally, if McKesson were correct that it needs 1.5 *years* to tally information about a recalled drug, it is hard to see how it can discharge its obligations to promptly provide such data to the FDA upon request. *See, e.g.*, 21 U.S.C. § 360eee-1(c)(4)(B)(i)(III), *see, also*, Ex. A to Pls. Ltr. (ECF 383), at¶ 36. It also must be noted that Plaintiffs' request for this data is not novel; these very same Wholesaler Defendants have produced similar data in other litigation. *See, e.g.*, *In re Androgel Antitrust Litig. (II)*, No. 1:09-MD-2084, 2012 WL 12895205, at *1 (N.D. Ga. Mar. 29, 2012).[21]

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[19] This, of course, is of no surprise, as Amerisource Bergen's own declarant Matthew Sample has previously discussed publicly how *all three wholesalers* have achieved "sub-second" speed in capturing transaction data between manufacturers, wholesalers and retail pharmacies. *See* SUB-SECOND RESPONSE TIME, AGGREGATION AMONG REQUESTS FROM WHOLESALER DISTRIBUTORS (Jan. 17, 2017, *available at* https://www.lspedia.com/2017/01/17/sub-second-response-time-aggregation-among-requests-from-wholesale-distributors/ (last visited June 28, 2020)).

[20] While McKesson claims it would take 3,336 hours to produce the data requested by Plaintiffs, each and every retail pharmacy customer of McKesson can pull data, queried by no fewer than 100 different fields, and receive reports instantaneously for their purchases. *See* MCKESSON INVOICES, REPORTS, IMPORTS & DOWNLOADS FIELD DEFINITIONS, *available at* https://newordering.mckesson.com/SMOnline/help/Field_Definitions.pdf (last visited June 28, 2020).

[21] "By April 2, 2012, the National Wholesalers shall produce all purchase and sales data on a drug by drug basis for AndroGel from January 1, 2006 to the present, Wellbutrin XL and its generic

Duplication. Wholesaler Defendants' final argument is that they should not have to produce anything because Manufacturer and Retail Pharmacy Defendants are producing their own respective data. As an initial matter, it remains to be seen what data the Manufacturer and Retail Pharmacy Defendants may produce. Beyond that, a named party does not get a pass in discovery from having to produce records in their *own* possession simply because another party might be producing some overlapping records, or documents with some overlapping data. Wholesaler Defendants make no showing that their own data is entirely duplicative of Manufacturer and Retail Pharmacy Defendants' data. In fact, despite Plaintiffs' proactive requests, Plaintiffs and the Court cannot even make this determination because these different tiers of defendants largely have not even produced exemplar hard-copy transactional documents (let alone electronic data) that could be compared. Further, data in Wholesaler Defendants' own unique possession, such as their inventory data, reside solely in their own hands. Simply put, Wholesaler Defendants fail to carry their burden that their production of their own data is unreasonably cumulative or duplicative of other defendants' potential forthcoming data productions.

D. Pricing (Sales and Cost) Data

Request No. 2 seeks the gross and net prices paid for the valsartan.[22] Request No. 4 seeks the gross and net prices at which Wholesaler Defendants sold valsartan to downstream purchasers.[23] Collectively, these two requests seek data showing how much Wholesaler Defendants paid for valsartan, and in turn how much they sold it for to downstream purchasers.

As with the pricing data sought from Retail Pharmacy Defendants, Plaintiffs reasonably seek this data to calculate Wholesaler Defendants' damages for unjust enrichment or disgorgement; that is, profits in the context of what they paid. To do that, Plaintiffs need to know these defendants' profits (i.e., the difference between their sales of valsartan and their costs to obtain valsartan).

Wholesaler Defendants make the same meritless arguments as to pricing data that they do as to tracing data. All of these arguments – Rule 12(b)-type arguments, proportionality, confidentiality, duplicativeness, undue burden – should be rejected for the same reasons as those

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equivalents from January 1, 2004 to the present (to the extent such data is still available), and Monopril HCT and its generic equivalents from January 1, 2002 to the present (to the extent such data is still available) in the manner maintained in the regular course of business…. Further, the National Wholesalers shall provide a written description of the data and data fields for the purchase and sales data produced herein. To the extent Defendants have reasonable questions about the descriptions, the National Wholesalers shall use reasonable efforts to address such questions in writing in lieu of a deposition on the data."

[22] "The gross and net price paid by you for VCDs identified in Request No. 1."

[23] "The gross and net price paid by purchasers to you for VCD sales identified in Request No. 3."

discussed *supra* Part II.C. The only different argument relates to relevance. Wholesaler Defendants argue pricing data is irrelevant because disgorgement is not an available remedy, based on their own pre-discovery rendition of the propriety of their conduct and the factual landscape. *See* ECF 478 at 5. This argument should be rejected for the same reasons discussed with respect to Retail Pharmacy Defendants in *supra* Part I.A. To briefly reiterate, disgorgement is an available equitable remedy within the Court's inherent power, in addition to being expressly authorized under certain claims (e.g., unjust enrichment or violations of state consumer fraud statutes). In this connection, Wholesaler Defendants' lengthy recitation on the availability of disgorgement under New Jersey law not only ignores claims under the laws of the other states and territories, but is substantively incorrect. *See, e.g.*, *Hudock v. LG Electronics, U.S.A., Inc.*, No. 16-1220, 2020 WL 1515233 (D. Minn. Mar. 30, 2020) (certifying New Jersey unjust enrichment class and Minnesota consumer protection statute class). Additionally, it is wholly premature since Plaintiffs do not know what will be learned in discovery as to their knowledge and conduct. But that is an issue to be addressed at the motion to dismiss and summary judgment phases.

E. Miscellaneous

Just this last week, after of months of negotiation, Wholesaler Defendants asked Plaintiffs to tell *Wholesaler Defendants* which of their own transactional exemplar documents Plaintiffs want. Plaintiffs' original draft requests dating back to December 2019 identify the types of transactional documents Plaintiffs have long-sought, the purpose of which was to narrow the burden to all defendants vis-à-vis data each tier of defendant might need to produce. That Wholesaler Defendants cannot even proffer a couple of transactional documents – invoices, bills of lading, etc. – is indicative of their foot-dragging and intention to dodge discovery in this litigation for as long as possible until ordered to participate.[24] Enough is enough. The time has

[24] Wholesaler Defendants are not alone in this apparent gamesmanship. Months ago, in February 2020, Plaintiffs told both Wholesaler and Retail Pharmacy Defendants that among the exemplars they could produce were "EDI 867 Product Transfer and Resale Reports." EDI refers to an industry-recognized electronic data transmission standards. Both sets of defendants said they never heard of EDI 867 reports. As it turns out, Plaintiffs' own investigation suggests these defendants use several other EDI reports. CVS, for instance, uses EDI 810, 812, 820, 824, 830, 846, 850, 860, 864, but apparently not 867. *See, e.g.*, CVS Mapping Specifications, https://cvssuppliers.com/edi-information/technical-specifications (last visited June 28, 2020). McKesson appears to use EDI 850, 855, 856, 810, and 832, but not 867. *See* PHARMACEUTICAL ORDERING AND SYSTEMS INTEGRATION, *at* https://www.mckesson.com/Pharmaceutical-Distribution/Data-Integration/ (last visited June 28, 2020). And while they professed that they never heard of EDI 867s, both Amerisource Bergen and Cardinal Health appear to use EDI 867s, among other EDI reports. *See* AMERISOURCE BERGEN MANUFACTURER PACKAGING AND LOGISTICS REQUIREMENTS GUIDE, *available at* https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/manufacturer-logistics-guideline-final-v14.pdf?la=en&hash=5297B4C716DBBE9A956F31CD2B194BD165F97465 (last visited June 29, 2020); Cardinal Health Distributor Policies and Procedures, *available at* https://www.cardinalhealth.com/content/dam/corp/web/documents/Policy/cardinal-health-distributor-policies-and-procedures.pdf (last visited June 29, 2020). Plaintiffs should not be forced

come for Wholesaler Defendants to approach party-discovery in this matter and produce the sharply narrowed set of data and documents attached as Exhibit C to Plaintiffs' opening letter brief.

Respectfully,

ADAM M. SLATER

cc: All Counsel (via CM/ECF)

to guess the correct three-digit data report as a perquisite to these defendants' production of them for sampling purposes.